Summary of written comments
From IAC members

I. Simple Summary of three responses to questions (see below for exact text responses):

1. Should the criteria be weighted? 2 no and 1 yes and 1 – Add another criteria stating that no vaccine containing mercury should be recommended. Make these criteria mandatory (see more detail on this response below in MM's response to #1)

2. Should all of the criteria apply to each antigen? 4 yes (NOTED counted MM's response as a yes)

2b. If not, should some of the criteria be mandatory?

2c. If so which ones?

3. How should we rate the criteria against the antigen? 1 suggestion for an algorithm approach (see more detail on this response below in MM's response to #3)

4. Should we use a scale or just pass/fail? 2 scale and 1 pass/fail

II. 4 respondents:

Bev Young Reed (parent) = BYR

Don Sloma (child advocate) = DS

Janna Bardi (state agency) = JB

Michele Murburg (parent) = MM

III. Written responses to questions:

1. Should the criteria be weighted?

Yes - BYR

I don't think so. The first batch (effectiveness) seem more or less necessary to any serious consideration of a vaccine and I would say at the end of the day, one would have to find a vaccine passed each of these criteria, but that is less black and white than it might appear. For example, how bad are the side effects? What if it isn't that effective, but the disease is universally fatal and spreading rapidly and there is no better prevention? What is the bar for cost effectiveness? 1:2? 1:10? I don't think a strict weighting system is worth devising to account for all this nuance. I think just putting these criteria out there for the Board to consider, to focus discussion, is adequate. DS

I do not feel the criteria should be weighted JB

[Response included under question 1] Re: the Mercury issue: As a parent, I would urge an additional criterion stating that no vaccine containing mercury should be recommended for,

required for school admission of, or administered to, any child of any age in Washington State. I am surprised that no mention is made of the mercury issue in the review of state policies. However, a number of states have laws banning mercury in vaccines that are given to children-- which may explain why the issue did not crop up as a criterion for State Health departments to use. In other words, since the matter has been legislated in a number of states, the absence of mercury from childhood vaccine preparations is likely assumed as an existing condition by the Boards of Health in those states, and not stated as a separate criterion. (See http://www.nomercury.org/state_legislation.htm) for information on states that have laws regarding mercury in vaccine preparations.

After doing further reading and inquiry, and learning that organic mercury in the form of thimerosol is still present in a number of vaccines (http://www.vaccinesafety.edu/thi-table.htm), that thimerosol is unnecessary to preserve antigen, that thimerosol is only used to prevent bacterial contamination in multi-dose vials (but is nonetheless present in some single dose pre-filled syringes), I think we need to add a criterion specifically about mercury. I think any vaccine to be required for children in Washington (or even provided as a recommended vaccine for any subgroup of children-- ie flu vaccine for asthmatics), should be mercury free. There is simply no acceptable reason for administering a known neurotoxin to children, or anyone else, along with a vaccine antigen-- even if the mercury doses involved are thought to result in "acceptable" levels of this toxin (and there is something oxymoronic about defining "acceptable levels" of a lethal toxin). There exists not a single study that shows that even low doses of administered mercury have no adverse effects on the human brain (I have years of experience as a psychiatrist and neuroscientist, and the studies that would prove or disprove that hypothesis simply have not been done-- nor can they ever be done). Whether the evidence that thimerosol is linked to Autism-spectrum disorders and ADHD is currently inconclusive or not, whether the existing studies of that link are flawed or not, there is still no unavoidable and compelling reason why Thimerosol should be put into vaccines. Single dose packaging would eliminate the need for it, and any inconvenience caused by single dose packaging is easily outweighed by the potential risk of neurotoxicity and, even the risk of parental perception that mercury in vaccines is harmful to their children-- which may lead many parents not to have their children vaccinated. Arguments that thimerosol-containing vaccines should be allowed because the diseases they prevent are serious is based upon the flawed premise that thimerosol is necessary to the vaccine preparation. I think the requirement that vaccines administered to any child of any age, whether the vaccine is required or not, contain no mercury, should be "written in stone". In other words, the criterion should be applied "pass-fail", and a fail should mean the vaccine doesn't get recommended or even administered in Washington State. As far as I can tell from reading the chart on the Johns Hopkins website, there are two drug companies, Sanofi Pasteur and Evans, still putting it into vaccines. They need to stop, and if they know that thimerosol-containing preparations will not be accepted for purchase, they will stop producing them and start producing mercury-free vaccine preparations. MM

1a. If so, what are your recommendations?

We should look at the whole picture. We need to build criteria that will not alienate parents, and will keep our children safe. I felt like we were on the right path at the meeting. We had a lot of good ideas, and direction. BYR

2. Should all of the criteria apply to each antigen?

Yes – BYR

I think all criteria should be considered against each antigen and applied as appropriate. As stated, yes. DS

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I feel all criteria should apply to all vaccine preventable diseases (VPD) for which there is a school or child care requirement – JB

[Response included under question 2] I am not sure that breaking the criteria down into pass/fail or weighting them is as useful as, perhaps, incorporating the criteria into an algorithm for evaluating the candidate vaccines. For example, of the list of criteria on the website, there was only one that looked to me like it needed to be pass/fail. MM

2b. If not, should some of the criteria be mandatory?

Most if not all of the effectiveness ones should be, but as noted above, the determinations in those criteria are shades of grey. So to keep this simple and honest, i would say no. DS

2c. If so which ones?

3. How should we rate the criteria against the antigen?

I am not sure on this one. – BYR

I think a pass/fail scale should be used for each VPD. And I think all criteria should be passed before implementation (no weighting, no adoption if there is a "no" on any criteria).

Here's my thinking: The criteria for school and child care entry requirements is for use in a non-emergency situation. I am making the assumption that other decision making authority would kick-in if we were ever in an emergency situation (WAC 246-110). So, in a non-emergency situation, the processes that are currently in place to make a vaccine part of the recommended schedule (by ACIP) will cover the criteria 1 through 4 and may also include 5 and 6. The WA State Vaccine Advisory Committee will also review and make a decision on implementation in WA based on effectiveness and disease burden criteria. Even with those 2 groups addressing these criteria, I think these are important criteria for the SBOH to use in their consideration of the requirements needed. The Board has a responsibility to look at those criteria themselves. So, items 1 through 6 will pass for any vaccine that is a part of the recommended schedule, made available through the VFC program and made available by the state of WA.

That brings us to the implementation criteria. If the Board wants the rule to be followed, I think all these criteria must be passed before adoption of a school or child care requirement for protection from a VPD. If the criteria for acceptability, administration, and cost are not met, it means the requirement will be less likely to be followed/enforced. If a problem is identified with criteria 7, 8 r 9, I think the Board and the department would want to look for a solution to the problem before adopting the requirement. – JB

a. vaccine effectiveness (needs to produce an immune response in better than X% of recipients, and needs to prevent disease in the face of a known challenge in Y% of recipients): the percentage, however, would likely be very different with different diseases, different epidemic scenarios, and vary based upon the availability of alternative vaccines and treatments. But in general, vaccines need to be effective, or why give them?

Thinking of the algorithm approach, maybe it could work something like the following (what is written below is just a a point of departure for discussion of a potential algorithm):

A) First tier screening:

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1) Disease or causal agent exists in or is likely to be introduced into Washington State. There is a significant risk of outbreak and/or transmission: Yes-- proceed. No-- Don't recommend.

2. The disease is associated with serious morbidity and/or mortality in a significant percentage of patients: Yes-- proceed. No-- proceed to second tier screening

3) Vaccine is effective in preventing disease. Yes-- proceed. No-- don't recommend.

4) The disease can be adequately prevented without the Vaccine. Yes-- don't recommend. No-- proceed.

5) The disease can be treated effectively and safely in unvaccinated patients using existing therapeutic agents. Yes-- don't recommend. No-- proceed.

6) The vaccine causes avoidable exposure to a known toxin (eg mercury): Yes-- don't recommend. No-- proceed.

7) The vaccine is associated with a very small risk of morbidity and mortality compared with the disease. Yes: proceed. No: don't recommend

8) The vaccine is associated with significant risk of morbidity and mortality compared with the disease itself, but the risk of the disease is very high so that the overall morbidity and mortality would be significantly lower with the vaccine than with the disease. Yes: proceed. No: don't recommend.

9) The cost of the vaccine is affordable: Yes-- recommend and require; No-- recommend but don't require????

Second tier screening:

1) The disease is associated with low rates of morbidity or mortality, but is associated with other losses (absenteeism from school, etc.) yes--proceed. No: don't recommend.

2) The vaccine is inexpensive. Yes-- proceed. No: don't recommend.

3) The vaccine is easily administered and requires only a single dose. Yes-- proceed. No-- proceed to third tier screening.

Etc... with further refinements. -- MM

4. Should we use a scale or just pass/fail?

I feel that a scale would be good. 1-5 or 10 if the antigen has 8 or higher on the scale then it would pass? I feel that this is a little more giving on both sides. – BYR

Because of the comments above, I would suggest a simple scale, not pass/fail. A scale of one to five or one to ten, on each criteria. But don't combine or weight them or try to combine them. Just look at each "grade" in each criteria and use that as a basis for a final decision on whether to mandate. DS

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